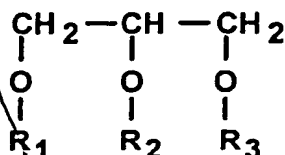


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Claims

1. Tuberculosis (TB) vaccine composition comprising,
 5 as adjuvant, one or more substances selected from
 a) monoglyceride preparations having at least 80 % monoglyceride content
 and having the general formula



wherein R_1 and R_2 is H and R_3 is one acyl group containing from 6 to 24 carbon atoms, and where the acyl chains may contain one or more unsaturated bonds, together with one or more substances selected from

- 15 b) fatty acids of the general formula



where "n" may be varied between 4 and 22, and where the acyl chain may contain one or more unsaturated bonds, and

as immunizing component, inactivated *Mycobacterium tuberculosis* bacteria.

- 20 2. TB vaccine composition according to claim 1, wherein the *M. tuberculosis* bacteria are heat killed or formalin killed.

3. TB vaccine composition according to claim 1 or 2, wherein the adjuvant has a monoglyceride preparation content of at least 90 %, preferably at least 95 %, and the acyl chains of the monoglyceride preparation contains 8 to 20 carbon atoms, preferably 14 to 20 carbon atoms, and the acyl chains optionally contains one or more unsaturated bonds.

4. TB vaccine composition according to any one of claims 1 - 3, which further comprises pharmaceutical excipients selected from the group consisting of biocompatible oils, physiological saline solution, preservatives and osmotic pressure controlling agents, carrier gases, pH-controlling agents, organic solvents, hydrophobic agents, enzyme inhibitors, water absorbing polymers, surfactants, absorption promoters, and anti-oxidative agents.

Sub
a1

5. TB vaccine composition according to claim 3 or 4, wherein the adjuvant is a mixture of mono-olein and oleic acid, and possibly soybean oil, and the immunizing component is heat-killed *M. tuberculosis* bacteria.

5 6. TB vaccine composition according to any one of claims 1-5, wherein the composition is formulated into a preparation for mucosal administration.

7. TB vaccine composition according to claim 6, wherein the mucosal administration is selected from nasal, pulmonary, oral and vaginal administration.

8. Aerosol or spray package comprising a TB vaccine composition according to any one of the claims 1-7.

10 9. Nose-drop package comprising a TB vaccine composition according to any one of the claims 1-7.

10. A method of vaccinating a mammal against Tuberculosis (TB) which comprises mucosal administration to the mammal of an protection-inducing amount of a TB vaccine composition according to any one of claims 1-7.

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